# Arizona Vaccine News

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## VACCINE NEWS

### FDA Gives Rotavirus Vaccine Recommendations
- The FDA recommends resuming use of GSK's Rotarix® and continuing to use Merck's RotaTeq®.
- The FDA had recommended temporary suspension of Rotarix® in March 2010 after discovering DNA from porcine circovirus type 1 (PCV1) in the vaccine.
- PCV1 was found both in the master cell banks and in the working cell banks. Subsequently PCV1 and porcine circovirus type 2 (PCV2) were found in RotaTeq®.
- PCV1 does not cause illness either in pigs or humans. PCV2 does not cause illness in humans but may cause illness in pigs.
- One possible source of the porcine virus is the porcine trypsin that was used in cell cultures in the 1990's. At that time the trypsin was not

irradiated. Trypsin samples from that time are not available to test this hypothesis.

- These new recommendations are based on safety data from studies in tens of thousands of children, safety data from post marketing reporting, a thorough review of the literature, the evidence that neither PCV1 nor PCV2 cause disease in humans, and the demonstrated benefit that rotavirus vaccines prevent hospitalizations and deaths.
- The FDA and the CDC will be working with the manufacturers to do follow up studies and perform ongoing testing to understand the origin of the porcine virus DNA and to monitor for any possible undetected safety concerns.
- Rotavirus causes severe disease in infants in the US. Every year rotavirus causes an estimated 20-60 deaths, 55,000-70,000 hospitalizations, 205-272,000 emergency department visits, and 410,000 outpatient visits.
- Since scientists have never identified any human disease caused by PCV1 or PCV2, the safest choice is to continue to offer rotavirus vaccine to infants.
- Details of the updated FDA recommendations can be found at www.fda.gov.
- CDC has updated the rotavirus VIS to reflect these new recommendations. http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf

**Forecasting Pneumococcal Vaccine Has Been Adjusted in ASIIS**

ASIIS forecasting has been adjusted to include new recommendations for Prevnar 13® (PCV13). Therefore, some patients may be forcasted to receive more than just four doses of pneumococcal conjugate vaccine. For example, in a patient who received 4 appropriately spaced doses of Prevnar 7®, ASIIS will show that a 5$^{th}$ dose is needed at least 8 weeks after the fourth dose.

ASIIS is not able to know if a patient has a medical condition that puts them at high risk for invasive pneumococcal disease. Children with underlying medical conditions may need an additional dose of PCV13 or may be recommended to receive PCV13 at an older age than usual. ASIIS will not be able to precisely forecast pneumococcal conjugate vaccinations in these children. Please refer to the updated recommendations for PCV13 that can be found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm

**Prevnar 13® Creates a More Complicated Vaccination Schedule for Children with High Risk of Invasive Pneumococcal Infections**

- Pneumococcal vaccine recommendations have become more complicated with the Advisory Committee on Immunization Practices' recommendations that Prevnar 13® (PCV13) now replace Prevnar 7® (PCV7.
- There are new recommendations for children at high risk for invasive pneumococcal disease due to underlying medical conditions and detailed instructions on how to transition from PCV7 to PCV13.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm

**Principles of Transitioning to PCV13**

General Principles

- PCV13 replaces PCV7 in the pneumococcal vaccine series.
- PCV13 should be given to all children ages 2-59 months who are healthy and for all high risk children ages 2-71 months who have underlying medical conditions that increase their risk for invasive pneumococcal disease.
- Children who are already fully immunized with PCV7 should receive a single dose of PCV13
- For **healthy children** from infancy through 59 months PCV13 is recommended at the same ages, with the same intervals, with the same number of doses for the infant series and the 12-15 month booster dose as was given for PCV7
    - Age at first dose 2-6 months: 3 doses, 6-8 weeks apart, 1 booster dose at 12-15 months of age
    - Age at first dose 7-11 months: 2 doses, 6-8 weeks part, 1 booster dose at 12-15 months of age
    - Age at first dose 12-23 months: 2 doses, 6-8 weeks apart
    - Age at first dose ≥ 24 months: 1 dose of PCV13
- Routine use of PCV13 is not recommended in healthy children aged ≥ 5 years old.
- For **high risk children** with underlying medical conditions that increase their risk for invasive pneumococcal disease, PCV13 dosing is the same as the schedule for healthy children (see above) except for ages 24 -71 months
    - Age at first dose ≥ 24 months: 2 doses of PCV13

Dosing by Current Immunization Status

- Children who are already fully immunized with PCV7
    - Give one dose of PCV13 at least 8 weeks after the last dose of PCV7
        - Through age 59 months in healthy children
        - Through 71 months In high risk children with underlying medical conditions that put them at risk for invasive pneumococcal disease
- Children who have never received PCV7
    - Infants: Give PCV13 according to the same schedule as PCV7
    - Ages 12-23 months: Two doses PCV13 at least 8 weeks apart
    - Ages ≥ 24 months
        - Healthy children 24-59 months: One dose of PCV13
        - High risk children 24-71 months Two doses of PCV13
- Children who are incompletely immunized (those who started PCV7 immunization but have not yet completed the series)
    - Continue pneumococcal conjugate series with PCV13 to finish the standard series

    - Only one dose of PCV13 is needed for children 12-23 months who received 2-3 doses of PCV7 before age 12 months
    - Children 12-23 months who received only one dose of PCV7 before 12 months
        - Give two doses of PCV13 at least 8 weeks apart
    - Children ≥ 24 months who received any incomplete schedule of pneumococcal conjugate vaccine
        - Healthy children 24-59 months: One dose of PCV13
        - High risk children 24-71 months: Two doses of PCV13 at least 8 weeks apart

- High risk children ages 6-18 years
    - May receive one dose of PCV13 even if they had been fully vaccinated with PCV7 and/or if they had received Pneumovax® (23-valent pneumococcal polysaccharide vaccine).
    - Note: PCV13 contains serotype 6A which is not in either PCV7 or Pneumovax®.

For full details on the updated recommendations for Prevnar 13®, please see http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5909a2.htm

**Fluzone® High-Dose Licensure**

- Elderly patients do not have as vigorous of an antibody response to influenza vaccination as younger patients and thus they are at higher risk of infection in spite of vaccination.
- Elderly people have better antibody responses to influenza vaccine when they are given vaccines containing a larger dose of antigen.
- The FDA has just licensed Fluzone® High-Dose (Sanofi Pasteur) which has four times the amount of antigen as found in regular seasonal influenza vaccines.
- This trivalent inactivated vaccine will contain the same three strains recommended for seasonal influenza. However, instead of having 15 mcg of each antigen there is 60 mcg of antigen for each of the three influenza vaccine strains.
- Fluzone® High-Dose will be available this fall for patients 65 years and older for seasonal influenza vaccination.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm195483.htm

## VACCINE LITERATURE

**US Hospitals (and Pediatricians) Falling Short on Perinatal Hepatitis B Prevention**

A study in the April 2010 issue of Pediatrics looked at how well hepatitis B vaccine policies were carried out in US hospitals.

- For infants of hepatitis B surface antigen-positive mothers:
    - Only 62.1% received both hepatitis B vaccine and hepatitis B immunoglobulin within 12 hours
    - 13.7% were unvaccinated

    - 19.7% did not receive hepatitis B immunoglobulin before hospital discharge.
- For infants born to mothers of unknown hepatitis B surface antigen status
    - Only 52.4% were vaccinated within 12 hours of birth
    - 20.1% were unvaccinated before discharge.

http://pediatrics.aappublications.org/cgi/reprint/125/4/704

## VACCINE PREVENTABLE DISEASE ALERTS

### Measles Outbreak in South Africa a Threat to World Cup Attendees

- Soccer fans traveling to southern Africa to attend the 2010 World Cup (held June 11-July 11, 2010 in South Africa) should make sure that they are fully vaccinated against measles.
- Since January 1, 2009, South Africa has had more than 11,000 cases of measles.
- Other countries in southern Africa (Botswana, Namibia, Swaziland, and Zimbabwe) have also reported recent measles outbreaks.

http://www.cdc.gov/measles/travel-worldcup.html

### Measles Outbreak Continuing in British Columbia, Canada

- Measles cases continue to be reported in British Columbia (B.C.) with a total of 83 cases reported through May 10, 2010.
- The majority of cases are unvaccinated or had unknown vaccination history. Some cases were unvaccinated for philosophical reasons.
- Ages of measles cases range from 5 months to 64 years (mean 22 yrs) with the largest percentage of cases to date among those 25-29 years of age; followed by children < 5 years of age.
- Additional and ongoing information is available at: http://www.bccdc.ca/resourcematerials/newsandalerts/healthalerts/MeaslesMarch30.htm

## VACCINE RESOURCES

### New Vaccine Information Sheet (VIS) for Pneumococcal Conjugate Vaccines

CDC has posted a new VIS for pneumococcal conjugate vaccine that is specific to Prevnar 13® (PCV13). Provider should begin to use this VIS immediately.
http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-pcv.pdf

### 17th Annual AZ Immunization Conference on May 18 & 19, 2010

The 17th Annual Arizona Immunization Conference will take place on Tuesday and Wednesday, May 18 &19, 2010 at the Black Canyon Conference Center, 9440 N. 25th Avenue, Phoenix, AZ 85021. Registration for the conference is closed. However, presentations from the conference will be posted on the Arizona Immunization Program Office website at
http://www.azdhs.gov/phs/immun/index.htm

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